

Final Small Business Economic Impact Statement for Rules Concerning

WAC 246-919-605 Use of Lasers, Light, Radiofrequency, and Plasma Devices as Applied to the Skin by Physicians

and

WAC 246-918-125 Use of Lasers, Light, Radiofrequency, and Plasma Devices as Applied to the Skin by Physician Assistants

1. Briefly describe the proposed rule.

There are many offices and clinics in the state of Washington providing skin treatment or hair removal using laser, light, radiofrequency and plasma (LLRP) devices. Some offices and clinics have a physician on site, some have a physician off-site, and some have no physician involvement at all. Since the Commission's authority is limited to governing physicians and physician assistants, the Commission has no authority over clinics that do not employ a physician or physician assistant. The Commission understands that some physicians employ appropriately licensed persons, such as physician assistants or registered nurses, to use the devices. The Commission is concerned that some physicians are employing persons whose legal scope of practice does not include the use of prescriptive devices on patients. This is analogous to an unlicensed person dispensing prescription medications.

The Commission believes when used appropriately, these devices are generally safe and relatively easy to operate. But the potential for patient injury with untrained, inappropriate, or negligent operation is significant. Several states have created rules regulating the use of LLRP devices. The Commission wishes to clarify this area of medicine, set minimal standards for the use of such devices by physicians and physician assistants in our state, and ensure that persons using these devices are operating within their legal scope of practice.

The adopted rules:

- Provide an effective date of March 1, 2007 giving individuals time to come into compliance with adopted rules.
- Define Laser, Light, Radiofrequency, and Plasma Devices (hereafter LLRP devices) as medical devices (a) that use a laser, non-coherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue and (b) are classified by the Federal Food and Drug Administration (FDA) as prescription devices;
- Provide that a physician or physician assistant must use an LLRP device in accordance with standard medical practice;
- State that the use of an LLRP device is the practice of medicine;
- Require a physician or physician assistant to be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and to remain competent for as long as the device is used;
- Require a physician or physician assistant to, prior to authorizing treatment with such a device, take the patient's medical history, perform an appropriate physical examination,

make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent (including informing the patient that a non-physician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record;

- Permit a physician or physician assistant to delegate use of the device to a properly trained and licensed professional whose scope of practice permits the use of a prescriptive device
- Require the physician or physician assistant to develop a specific protocol for the licensed professional to follow;
- Prohibit a physician or physician assistant from delegating an LLRP for use on globe of the eye;
- Require the delegating physician to be on the immediate premises during the initial treatment to treat complications, if indicated;
- Permit the physician to be temporarily absent during treatment of patients with established treatment plans provided a local back-up physician agrees in writing to treat complications, is reachable by telephone, and can see the patient within sixty minutes;
- Require the delegating physician assistant to be on the premises during all treatment with an LLRP device;
- Provide that regardless of who operates the device, the physician is ultimately responsible for the safety of the patient;
- Require the physician to establish a quality assurance program; and
- Provide that the use of devices to penetrate and alter human tissue for a purpose other than to topically penetrate the skin constitutes surgery and is outside the scope of these rules.

2. Is a Small Business Economic Impact Statement (SBEIS) required for this rule?

Yes.

3. Which industries are affected by this rule?

The adopted rules will directly affect medical offices and clinics in the state of Washington providing treatment with LLRP devices as applied to the skin in which a physician or physician assistant is involved. The adopted rules regulate a physician and physician assistant's use and delegation of LLRP devices.

Although the proposed rules apply only to physicians and physician assistants, the proposed rules will affect beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices without physician or physician assistant supervision. Existing law does not permit estheticians or any person without prescriptive authority to operate these devices. DOH has taken action against estheticians and others for operating these devices. Despite this, the use of these devices by persons without prescriptive authority appears to be widespread. The adopted rules have brought attention to the fact that these people are operating outside the bounds of the law.

In response to the Commission's adopted rules, the Department of Licensing is in the process of adopting a rule that will permit estheticians to use these devices only under the supervision and delegation of a physician or physician assistant licensed under Chapter

18.71, 18.71A, 18.57, or 18.57A RCW. If the Department of Licensing rule is adopted, beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices will have to hire a physician or physician assistant to examine each patient, set up a treatment plan, and supervise the treatment.

SIC Industry Code and Title	# of Businesses	# of Employees	Average # of Employees for Smallest Businesses	Average # of Employees for Largest Businesses
			< 50 Employees	>= 50 Employees
8011 Offices and Clinics of Doctors of Medicine	2,821	43,659	7.9	154.2
8093 Specialties outpatient clinic	245	7530	9.3	113.5
8049 Offices and Clinics of Health Practitioners, Not Elsewhere Classified	913	5,450	4.5	102.9
7231 Beauty Shops	1,598	9,191	4.7	106.2
7299 Miscellaneous Personal Services	530	2668	6.0	No Large businesses

4. What are the costs of complying with this rule for small businesses (those with 50 or fewer employees) and for the largest 10 % of businesses affected?

There are potential costs due to the implementation of this rule. Practitioners who have an LLRP device in their office or clinic will have to be trained to use the device properly. The staff who is a licensed professional in which the use of LLRP devices are within their scope of practice will have to be trained to use the device properly if not already trained. A physician or physician assistant will have to see and examine each and every patient who wishes to undergo treatment with an LLRP device. The physician will have to contract with a back-up physician to provide treatment if there are complications. If a physician assistant delegates the use of an LLRP device, the physician assistant will have to be on site for each treatment. Each of these requirements may add to the cost of treatment with an LLRP device. On the other hand, the rules should decrease the cost of healthcare by reducing the severity or number of complications to patients.

During the rules process, public comments were made regarding the small business economic impact which required further review and research on the wages of physicians and physician assistant. This final SBEIS reflects those findings.

The rule will require additional training for the licensed professional using the LLRP devices. The manufacturer of the device frequently provides training at no cost to the purchasers of the device at the time of the initial sale. After the sale, new employees will need additional training. The cost of the training for physicians, physician assistants or new employed license professional is in the range of \$1250 to \$2500¹ depending on the

¹ Based on a sample of advertisements for laser training courses:

- o Esthetic Skin Institute, Inc (www.esiw.com)
- o Empire Medical Training (www.empiremedicaltraining.com)
- o Aesthetic Enhancement Institute (www.aeinstitute.biz)
- o CeLibre Medical Corporation (www.celibre.com)

type of devices. The rules also require the physician or physician assistant to be not only trained on the prescriptive devices, but also appropriately trained in physics, safety and techniques of the LLRP devices prior to using them. In order to maintain a Washington state license, physician or physician assistants are required to obtain continuing medical education every two (PAs) or four years (MDs). The assumption is that the cost for training of the physician or physician assistant is included in the cost of maintaining licensure and therefore has little or no impact to the practitioner.

The adopted rules will require the physician or physician assistant to complete the initial physical and history of the patient prior to initiating any treatment. The Commission believes it is the standard of care for a physician or physician assistant to examine a patient before developing any medical treatment plan. This medical cost will be borne by the patient or the patient's insurer.

The adopted rules require physicians and physician assistants to supervise the use of LLRP devices, which ultimately increases the cost for the treatments. A physician who delegates the use of an LLRP device must be on the immediate premises during the initial treatment. For subsequent treatments, the licensed professional may perform the treatments during "temporary absences" of the physician, so long as there is a back-up physician available by phone and accessible to see the patient within 60 minutes. When supervising, physician assistants must be on the "immediate premises" at all times.

The adopted rules will require the practitioner to delegate procedures only to trained and licensed professionals whose scope of practice allows for the use of the LLRP devices. A physician's office costs may increase by adding one physician assistant for 32 hours per week at a pay range from \$36.97² to \$48.76³ an hour. The physician assistant would be available to supervise other licensed personnel when the physician is not available or to be responsible for the initial patient history and physical examinations and create the appropriate treatment plans. The cost may potentially increase an additional \$1,183 to \$1,560 per week. For large physician clinics with physicians on site most of the patient hours, the clinic may need two additional physician assistants for 32 hours each which will increase the costs approximately \$2,366 to \$3,120.

The adopted rules may indirectly affect beauty salons, spas, boutiques or other small cosmetic businesses. The rules apply only to physicians and physician assistants. Other entities may take action against persons who are not physicians or physician assistants. The DOH has taken the position that the use of LLRP devices is the practice of medicine, and has issued cease and desist orders against licensed estheticians and persons with no license who are operating these devices without the supervision of a physician or physician assistant. The adopted rules will not affect DOH's ability to respond to complaints of unlicensed practice of medicine and issuing cease and desist orders and fines. However, the adopted rules, along with the rule under consideration by the Department of Licensing, will provide a pathway for estheticians to operate LLRP devices.

² Based on the U.S. Department of Labor May 2005 WA State Occupational Employment and Wage Estimates

³ Based on the American Academy of Physician Assistant 2005 Physician Assistant Income.

Beauty salons, spas, boutiques or other small cosmetic businesses who employ estheticians to use the LLRP devices without the supervision of a physician or physician assistants may come into compliance with the current law and the adopted rules by:

- Hiring a full time physician for 32 hours per week at a cost of \$135,250⁴ to \$204,672⁵ annual pay; or
- Hiring a part time physician to supervise 1-2 physician assistants. The assumed total cost for a small clinic opened 6 days per week may increase to \$4,350 per week. This includes:
 - A physician to be present to supervise the physician assistants and other personnel for 5-10 hours per week at \$65⁶ to \$123⁷ per hour for an average of \$650 to \$1,230 per week
 - Each physician assistant may overlap a 32 hour work week to supervise licensed professionals, complete histories and physicals, and direct all medical laser procedures increases the cost an additional \$2,366 to \$3,120.

The Commission does not have a sense of how many LLRP devices are being used by individuals without a professional license. Although the FDA requires prescriptive authority to purchase the medical laser devices, the unlicensed individuals are able to obtain the equipment through the second hand market. The FDA is focused on the manufacturers and not the regulation or enforcement of the end users.

The adopted rule will require a backup physician for a physician if not available. This is already a common practice among physicians.

5. Does the rule impose a disproportionate impact on small businesses?

The adopted rules do impose a disproportionate impact on small businesses as the table shows. The cost per average employee is much higher for small businesses as compared to large businesses.

SIC Industry Code and Title	Average # of Employees for Smallest Businesses	Average # of Employees for 10% of Largest Businesses	Costs of Rule Change Small Businesses	Costs of Rule Change Large Businesses	Average Cost Per Employee Small Businesses	Average Cost Per Employee Large Businesses
	< 50	>= 50	< 50	>= 50	< 50	>= 50
8011 Offices and Clinics of Doctors of Medicine	7.9	154.2	\$1,560	\$3,120	\$197.50	\$20.23
8093 Specialty outpatient clinics, nec	9.3	113.5	\$1,560	\$3,129	\$167.74	\$27.49
8049 Offices and Clinics of Health Practitioners, Not	4.5	102.9	\$1,560	\$3,120	\$346.67	30.32

⁴ Based on the U.S. Department of Labor May 2005 WA State Occupational Employment and Wage Estimates

⁵ Based on Salaries.com for physicians-family practice in Seattle, Washington.

⁶ Based on the U.S. Department of Labor May 2005 WA State Occupational Employment and Wage Estimates

⁷ Based on Salaries.com for physicians-family practice in Seattle, Washington.

Elsewhere Classified						
7231 Beauty Shops	4.7	106.2	\$4,350	\$4,350	\$925.53	40.69
7299 Misc. Personal Care Services	6.0	No large businesses	\$4,350	No large businesses	\$725.00	No large businesses

6. If the rule imposes a disproportionate impact on small businesses, what efforts were taken to reduce that impact (or why is it not “legal and feasible” to do so) by

The Commission’s significantly reduced the regulatory requirements of the first proposed draft that 1) required only licensed health care practitioners to use the devices, 2) required a physician assistant to be directly supervised during the use of the LLRP devices 3) required a physician to remain on site at all times, and 4) required only a physician to do the history and physical of the patient. The Commission collaboratively worked with the Department of Licensing, Washington State Medical Association, estheticians, and practitioners who employ individuals to do laser procedures. The proposed rules allows for 1) licensed professionals whose scope of practice includes the use of the LLRP prescriptive devices and who are supervised by a physician or physician assistant to perform procedures, 2) a physician assistant supervision as defined by the practice plan, 3) physicians may be temporarily absent if called away for an emergency under certain conditions, and 4) physician assistants to do history and physicals and treatment plans because this is already in their current scope of practice.

7. How are small businesses involved in the development of this rule?

Department staff worked closely with the Medical Commission, the Washington State Medical Association, persons using these devices, both licensed and non-licensed, and people associated with companies marketing devices to minimize the burden of these proposed rules. Several owners of affected businesses submitted written comments or attended Commission meetings to discuss the potential impact the proposed rules would have on their businesses. The Commission modified the proposed rules so that the impact would be as minimal as possible while still promoting safe medical care.

The Medical Commission has included the Department of Licensing Cosmetology Board during its rule process and continues to work with DOL staff to ensure public safety by both agencies. Licensed estheticians provided written comments during the rules process and attended the Commission’s public meetings to provide oral comments. There were multiple professions represented at the rules hearing and provided oral testimony.